

Laboratory Registration/Select Agent Transfer Program Application for Laboratory Registration

Information on Select Agent Toxins

Before beginning this section, do the following:

Review 42 CFR 72.6, including Appendix A and the Federal Register *Notice - Notice of Site Registration Fee Schedule...* (attached). Certain uses of the select agent toxins are exempt from the requirements of this regulation (see 42 CFR 72.6 subsection (h)). However, if you will be using toxins for one of the exempt purposes (e.g., inactivated for use as vaccines), but will be working with bacteria or recombinant DNA preparations that are select agents, you must complete the portions of this application package that describe your work with the select agent bacteria, etc, but you are not required to complete this section.

If you determine that you are required to register, refer back to the Background Information/Certification and Signature page of this application. Use the BMBL, the BMBL supplement page (see attachment), the *NIH Guidelines*, and 29 CFR 1910.1450, as appropriate to determine the laboratory safety requirements for the various types of work you will do with each of the select agent toxins you listed.

If you do the same type of work with several select agent toxins with the same safety requirements, in one laboratory, under the supervision of one principal investigator, you may consider those select agent toxins as one group and give us the required information for all of them on this form.

If your facility will work with several select agent toxins with different safety requirements, or the work will be done in several laboratories, photocopy this form as many times as necessary, then complete a different form for each group of select agents or laboratory.

Section 1

What select agent toxins will you describe on this form ?

List the toxins here: _____

What laboratory will you use for work with these select agents (Building, Room Number)? _____

Will you be doing only Clinical/Diagnostic work with these select agents? () Yes () No

Is your laboratory a CLIA regulated laboratory for purposes of work with the select agent(s) listed?
() Yes () No.

If yes, what is the CLIA registration number for this laboratory (or for your facility, if the facility has a single number)? _____

(If the only work you do with this select agent or group of select agents is covered by CLIA, you may be exempt from the requirements of 42 CFR 72.6. Refer to the regulation (Attachment 1))

Will you be working with isolates/concentrates or recombinant DNA of any select agents as part of your work with these select agent toxins? ☐ Yes ☐ No

(If you will be working with isolates/concentrates or recombinant DNA, complete the **Information on Select Agent Viruses, Bacteria, Rickettsiae, and Fungi** and/or the **Information on Select Agents Containing Recombinant DNA** sections of this application package, as appropriate.)

Will you use laboratory animals (e.g., mice, guinea pigs) for any of your work with these select agents? ☐ Yes ☐ No

Will you use large animals (e.g., sheep, cattle) for any of your work with these select agents? ☐ Yes ☐ No

Will you be doing any large scale (LS) ("production level") work with any of these select agents? ☐ Yes ☐ No

Section 2

Descriptions of laboratories and procedures for work with select agent toxins at your institution:

On a separate sheet:

State the name of the individual responsible for laboratory (e.g., principal investigator or laboratory supervisor).

Describe briefly (1-2 sentences) type of work being done with select agent(s) listed above.

Describe briefly (1-2 sentences each): 1) how you control access to laboratory area where these select agents are used, 2) how you ensure adequate training, and proficiency testing for personnel working with agent(s), 3) where you store the select agent(s) (e.g., location of refrigerators, freezers or other storage), 4) proposed method of disposal of select agent(s) when work is complete, and 5) method for managing a spill or accidental exposure to the select agent(s).

Attach a sketch/floor plan (not blueprints) for laboratory where work will be performed - show entry, location of fume hoods, BSC, incubators, freezers, autoclaves, and other equipment specified in the BMBL, *NIH Guidelines*, 29 CFR 1910, or other reference document as recommended for work with the toxin(s) listed here. Mark location of air intake and exhaust vents.

Describe the air-handling system for the laboratory where the work will be performed (e.g., single pass or re-circulation, type of filters, method for handling safety cabinet and fume hood exhaust)

Note - If you are using select agent bacteria and/or recombinant DNA in the course of your work with the toxins listed on this page, and have completed the **Information on Select Agent Viruses, Bacteria, Rickettsiae, and Fungi** and/or the **Information on Select Agents**

Containing Recombinant DNA sections of this application package, tell us that. You do not need to give us that information again in this section.

Section 3

Assessment of your laboratory based on recommendations of 29 CFR 1910.1450

The appendix to this application package contains a laboratory assessment instrument based on 29 CFR 1910.1450.

Under 42 CFR 72.6, the requirements of 29 CFR 1910.1450 must be met by laboratories working with select agent toxins, so you must complete the 29 CFR laboratory assessment instrument, or:

If yours is a DOD laboratory working under 32 CFR 626 and 627, you may substitute the relevant sections of that regulation. Attach a copy of the relevant section of the regulation, with a "Yes", "No" or "N.A." noted in the margin for each item, and the responsible facility official's initials on each page.

If your laboratory works with this select agent toxin under other federal regulations or guidelines (e.g., FDA, EPA or USDA), that have different requirements than 29 CFR 1910.1450, please complete as much of the 29 CFR 1910.1450 - based questionnaire as possible, and attach a copy of any other federal regulation or guideline, marked to show us where it differs from 29 CFR 1910.1450 and initialed by the responsible safety official.

Attach a copy of the completed **29 CFR 1910.1450 Laboratory Assessment Instrument** to this form. If you work with select agent bacteria or recombinant DNA in the course of your work with this select agent toxin, be sure that you have completed the appropriate **Information on Select Agent Viruses, Bacteria, Rickettsiae, and Fungi** and/or the **Information on Select Agents Containing Recombinant DNA** sections of this application package.